PAPER NUMBER

**PAPER** 

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/762,210      | 01/20/2004  | Ronald J. Berenson   | IVGN 837.5          | 2519             |

65841 7590 05/07/2007
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| 1651      |                 |
|-----------|-----------------|
| MAIL DATE | · DELIVERY MODE |

**EXAMINER** 

KIM, TAEYOON

**ART UNIT** 

05/07/2007

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  |  | Application   | on No.  | Applicant(s)   |          |  |
|--|--|---|---|--|----------|--|
| Office Action Summary  |  | 10/762,21   | 0   | BERENSON ET AL.  |          |  |
|  |  | Examiner  |   | Art Unit   |          |  |
|  | <u> </u>   | Taeyoon k   |   | 1651   |          |  |
| The Period for Re  | e MAILING DATE of this communication ply   | appears on the  | cover sheet with the co   | orrespondence addre  | ss       |  |
| WHICHEN - Extensions after SIX (6 - If NO perior - Failure to re Any reply re  | ENED STATUTORY PERIOD FOR RE /ER IS LONGER, FROM THE MAILING of time may be available under the provisions of 37 CFF.) MONTHS from the mailing date of this communication. d for reply is specified above, the maximum statutory per eply within the set or extended period for reply will, by state seceived by the Office later than three months after the ment term adjustment. See 37 CFR 1.704(b). | DATE OF TH<br>R 1.136(a). In no even<br>riod will apply and will<br>atute, cause the appl | IIS COMMUNICATION ent, however, may a reply be tim II expire SIX (6) MONTHS from to ication to become ABANDONEE | l. ely filed the mailing date of this comm 0 (35 U.S.C. § 133) |          |  |
| Status   |  |   |   |  |          |  |
| 2a)∭ This<br>3)∭ Sind  | ponsive to communication(s) filed on $\underline{24}$ action is <b>FINAL</b> . 2b) $\square$ To this application is in condition for allowed in accordance with the practice under   | This action is now  | on-final.<br>for formal matters, pro  |  | erits is |  |
| Disposition of   | of Claims  |   |   |  |          |  |
| 4a) 0<br>5)∭ Clai<br>6)⊠ Clai<br>7)∭ Clai  | m(s) <u>22 and 23</u> is/are pending in the ap  Of the above claim(s) is/are without  m(s) is/are allowed.  m(s) <u>22 and 23</u> is/are rejected.  m(s) is/are objected to.  m(s) are subject to restriction an   | drawn from cor  |   |  |          |  |
| Application F  | apers  |   |   |  |          |  |
| 10)∭ The<br>App<br>Rep   | specification is objected to by the Exam<br>drawing(s) filed on is/are: a) a<br>icant may not request that any objection to the<br>lacement drawing sheet(s) including the control<br>oath or declaration is objected to by the  | accepted or b)[<br>the drawing(s) b<br>rection is require                                 | e held in abeyance. See<br>ed if the drawing(s) is obje   | 37 CFR 1.85(a).<br>ected to. See 37 CFR 1                      |          |  |
| Priority unde  | r 35 U.S.C. § 119  |   |   |  |          |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |  |   |   |  |          |  |
| 2) ☐ Notice of D<br>3) ☑ Information   | references Cited (PTO-892)<br>rraftsperson's Patent Drawing Review (PTO-948)<br>Disclosure Statement(s) (PTO/SB/08)<br>)/Mail Date <u>3/26/07, 1/24/07</u> .   |   | 4) Interview Summary ( Paper No(s)/Mail Dat 5) Notice of Informal Pa 6) Other:                                  | e  |          |  |

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It is noted that the current application has been reassigned to the current examiner.

## Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Jan. 24, 2007 has been entered.

## Response to Amendment/Arguments

Applicant's amendment and response filed on Oct. 26, 2006 has been received and entered into the case.

Applicant argued that the cited reference does not anticipate the present invention because of the amendment made to the claims. However, this argument is not found persuasive because the amendment does not obviate the rejection. Applicant amended claims to have limitation of "simultaneous T cell concentration and cell surface moiety ligation". This limitation has been met by the method of Creson et al. because the method of Creson et al. utilizes a paramagnetic bead such as Dynabead M-450 which is used for simultaneous stimulation because of magnetic field applied to the beads coated with anti-CD3 and anti-CD28 antibodies to ligate and concentrate the

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cells having CD3 and CD28 ligands. Therefore, the new limitation in the amended claims are anticipated by the reference. As discussed below, a step of applying magnetic force (field) is an inherent method step associated with the method of Creson et al. to stimulate T cells with magnetic beads coated with anti-CD3 and anti-CD28 antibodies.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Creson et al. (1999).

Claims 22 and 23 are drawn to a method for activating and expanding a population of regulatory T cells by simultaneous T cell concentration and cell surface moiety ligation, comprising contacting a population of cells comprising regulatory T cells with a paramagnetic particle where first and second agents are co-attached, applying a magnetic force to drive T cell concentration and T cell surface moiety ligation to induce activation and expansion of regulatory T cells (claim 22); a limitation to the method wherein the first agent being an anti-CD3 antibody or an antigen-binding fragment thereof, and the second agent being an anti-CD28 antibody or an antigen-binding fragment thereof (claim 23).

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Creson et al. teach the activation and expansion of T cells using anti-CD3 and anti-CD28 antibodies attached to magnetic beads such as Dynabead M-450 (see p. 9338, Materials and Methods). Dynabead M-450 is a paramagnetic particle as disclosed in the specification of the current application (see p.30, lines 20-23). Although Creson et al. do not particularly disclose a step of applying a magnetic force to drive T cell concentration onto the beads via T cell surface moiety ligation, this step is inherently achieved by the method of Creson et al. using paramagnetic beads to stimulate T cells. Because the method steps of activating and expanding T cell populations with a magnetic bead coated with two agents (anti-CD3 and anti-CD28 antibodies) are the same, Creson et al. inherently teach the same process of applying a magnetic force as in the current application. Creson et al. therefore anticipates the step of applying a magnetic force as instantly claimed. The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) and In re Tomlinson, 363 F.2d 928, 150 USPQ 623 (CCPA 1966). See M.P.E.P. § 2112.02.

Although Creson et al. do not particularly disclose regulatory T cells, The "genus" T cells contain very few species comprising regulatory T cells. Given that, the generic T cell disclosure in Creson et al. is sufficiently specific to anticipate applicant's claimed

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invention though it is drawn to a species of T cells because one would at once envisage "regulatory T cells" when reading Creson et al.'s "T cell".

M.P.E.P. §2131.02 states "When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

## Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim Patent Examiner Art Unit 1651 Leon B Lankford, Jr Primary Examiner

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